

REMARKS

The present application has been reviewed in view of the Office Action dated December 27, 2007. Claims 1-35 are currently pending. By the present Amendment, claims 1, 19, 28, and 31 have been amended, and new claims 33-35 have been added for consideration. Applicant respectfully submits that these amendments add no new matter, are fully supported by the specification, and are allowable over the references of record. In view of the amendments made herein and the following remarks, early and favorable reconsideration and allowance of this application are earnestly solicited.

Claims 1-5, 7-9, and 12-32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,215,521 to Cochran *et al.* (hereinafter "Cochran") in view of U.S. Patent No. 5,480,404 to Kammerer *et al.* (hereinafter "Kammerer"). Applicant respectfully submits, however, that Cochran in view of Kammerer fails to suggest each and every element of claims 1-5, 7-9, and 12-32.

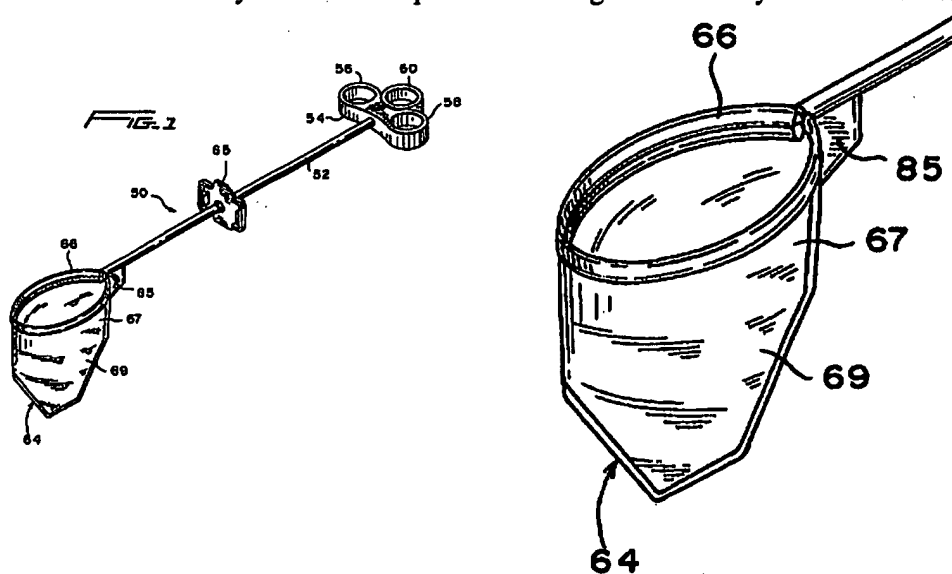
Claim 1 recites a tissue removal device that includes, *inter alia*, a bag that is "repositionable between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself" wherein the bag includes "at least one transverse fold extending at least partially from the first edge toward the second edge such that an angle less than 90° is defined relative to the longitudinal axis."

Cochran relates to an organ retrieval apparatus including an entrapment envelope that is inserted into an inflated body cavity through an elongate sheath. (*See* col. 8, lines 12-18).

Kammerer relates to a tissue retrieval instrument including an elongated support tube 52 having a finger grip 54 mounted to a proximal end thereof. (*See* col. 6, lines 6-8). At a distal end of the support tube 52, a collapsible pouch 64 is supported by a flexible belt 66 which is slidably received by the support tube 52. (*See id.* at lines 12-15).

In the Office Action, it was asserted that Cochran discloses each and every element of claim 1 but for the "at least one transverse fold" recited therein. Kammerer was relied upon for the disclosure of that concept.

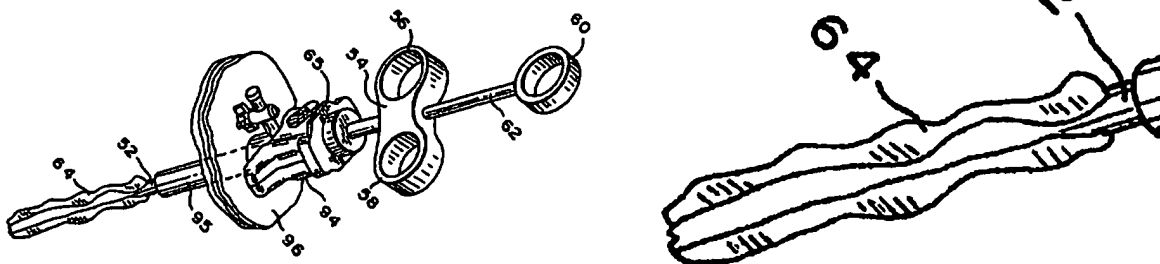
Kammerer's pouch 64 includes "a top straight portion 67 with substantially parallel sides and a bottom tapered portion 69 with converging sides," and as seen in FIG. 1 and the corresponding enlargement below, the pouch 64 is formed of a substantially uniform film of polymeric material to thereby define outer portions having substantially uniform surfaces.



The pouch 64 does not include “at least one transverse fold extending at least partially from the first edge toward the second edge such that an angle less than 90° is defined relative to the longitudinal axis,” as recited in claim 1.

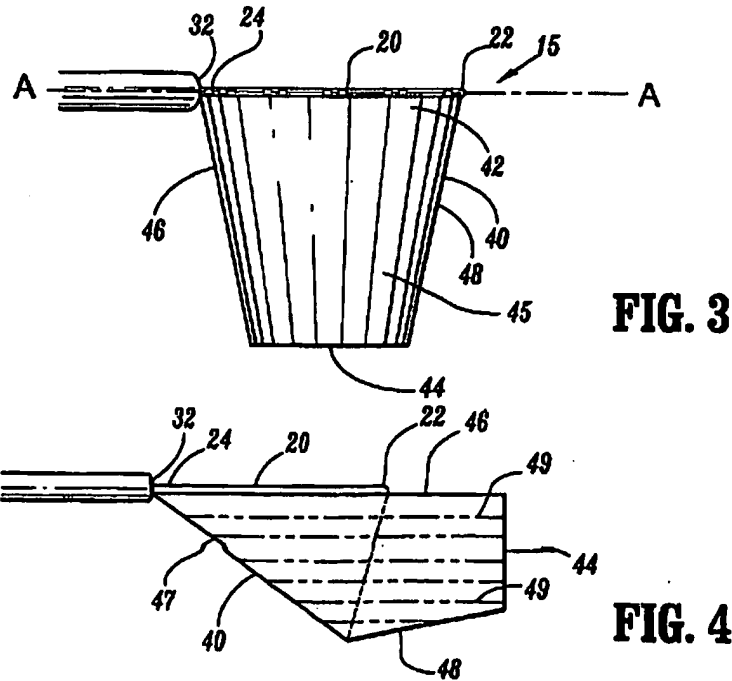
Moreover, Kammerer discloses that the pouch 64 is “slidably extendable through the support tube 52 for expanding the open end of the pouch 64 to receive the tissue and for drawing the open end closed to enclose the tissue in the pouch 64.” (Col. 6, lines 18-21). Applicant respectfully submits that the pouch 64 of Kammerer is simply collapsed and expanded during use as it is drawn in to, and forced out of, the support tube 52, as seen below in FIG. 10 and the corresponding enlargement.

FIG. 10



The pouch 64 is never folded, and therefore, is not repositioned between an “unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself,” as recited in claim 1. (Emphasis added). According to the present disclosure, the bag 40 is foldable along fold lines 49, for example, to achieve a final folded or second position of bag assembly 15 to prepare the bag assembly for packaging, as seen below in the transition between FIGS. 3 and 4. (See page 13, lines 15-18). The present disclosure states

that folding the bag 40 in this manner "has been found to produce a low profile folded bag, such that smaller diameter tubes can be used." (*Id.* at lines 18-20).



For at least these reasons, *inter alia*, Applicant respectfully submits that Kammerer fails to cure the deficiencies of Cochran. Accordingly, Applicant respectfully submits that Cochran in view of Kammerer fails to suggest each and every element of claim 1, and that claim 1 is allowable over Cochran in view of Kammerer. As claims 2-5, 7-9, and 12-18 depend either directly or indirectly from claim 1 and contain all the elements thereof, for at least the reasons set forth regarding the allowability of claim 1, *inter alia*, Applicant respectfully submits that claims 2-5, 7-9, and 12-18 are also allowable over Cochran in view of Kammerer.

Claim 19 recites a method of collapsing a bag of a tissue removal device including the steps of providing a minimally invasive tissue removal device having, *inter alia*, a bag that is “repositionable between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself,” and “folding the bag transversely with respect to the longitudinal axis such that a first, transverse fold is formed that extends at least partially from the first edge toward the second edge such that an angle less than 90° is defined relative to the longitudinal axis.”

As discussed above with respect to claim 1, Cochran in view of Kammerer fails to disclose a bag that includes a “transverse fold” or a bag that is “repositionable between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself,” elements which are also recited in claim 19. *A priori*, Cochran in view of Kammerer also fails to disclose a method which includes a step comprising “folding the bag transversely with respect to the longitudinal axis such that a first, transverse fold is formed that extends at least partially from the first edge toward the second edge such that an angle less than 90° is defined relative to the longitudinal axis.” (Emphasis added).

For at least these reasons, *inter alia*, Applicant respectfully submits that Cochran in view of Kammerer fails to suggest each and every element of independent claim 19, and therefore, that claim 19 is allowable over Cochran in view of Kammerer. As claims 20-27 depend either directly or indirectly from claim 19 and contain all the elements thereof, for at least the reasons

set forth regarding the allowability of claim 19, *inter alia*, Applicant respectfully submits that claims 20-27 are also allowable over Cochran in view of Kammerer.

Claim 28 recites a minimally invasive tissue removal device that includes an elongate shaft and a bag assembly operatively coupled to a distal end portion thereof. The bag assembly includes, *inter alia*, “a bag configured for repositioning between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself” wherein the bag is “folded over onto itself so as to form at least one transverse fold defining a fold axis, wherein the fold axis defines an angle between 0° and 90° relative to the longitudinal axis such that an axial length of the bag assembly is increased and a cross-sectional profile of the bag assembly is minimized when the bag is in the folded position.”

As discussed above with respect to claims 1 and 19, Cochran in view of Kammerer fails to disclose a bag that is “repositionable between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself” or a bag that includes a “transverse fold,” elements which are also recited in claim 28. Accordingly, Cochran in view of Kammerer also fails to disclose a bag having a transverse fold defining a fold axis wherein “wherein the fold axis defines an angle between 0° and 90° relative to the longitudinal axis such that an axial length of the bag assembly is increased and a cross-sectional profile of the bag assembly is minimized when the bag is in the folded position.”

For at least these reasons, *inter alia*, Applicant respectfully submits that Cochran in view of Kammerer fails to suggest each and every element of independent claim 28, and therefore,

that claim 28 is allowable over Cochran in view of Kammerer. As claims 29-30 depend either directly or indirectly from claim 28 and contain all the elements thereof, for at least the reasons set forth regarding the allowability of claim 28, *inter alia*, Applicant respectfully submits that claims 29-30 are also allowable over Cochran in view of Kammerer.

Claim 31 recites a minimally invasive tissue removal device for passage through a trocar that includes, *inter alia*, a bag that is “configured for repositioning between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself” wherein “the bag is folded over onto itself so as to form at least one fold extending along an that is substantially non-parallel and non-orthogonal to the longitudinal axis of the shaft.”

As discussed above with respect to claims 1, 19, and 28, Cochran in view of Kammerer fails to disclose a bag that is “repositionable between an unfolded position, in which the bag extends away from the bag support, and a folded position, in which the bag is folded onto itself” or a bag that includes a “fold,” elements which are also recited in claim 28. Accordingly, Cochran in view of Kammerer also fails to disclose a bag that is “folded over onto itself so as to form at least one fold extending along an that is substantially non-parallel and non-orthogonal to the longitudinal axis of the shaft.”

For at least these reasons, *inter alia*, Applicant respectfully submits that Cochran in view of Kammerer fails to suggest each and every element of claim 31, and therefore, that claim 31 is allowable over Cochran in view of Kammerer. As claim 32 depends directly from claim 31 and

contains all the elements thereof, for at least the reasons set forth regarding the allowability of claim 31, *inter alia*, Applicant respectfully submits that claim 32 is also allowable over Cochran in view of Kammerer.

Claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Cochran in view of Kammerer and further in view of U.S. Patent No. 5,899,694 to Summer (hereinafter "Summer"). Applicant respectfully submits, however, that Cochran in view of Kammerer and further in view of Summer fails to suggest each and every element of claim 6.

In the Office Action, it was asserted that Summer discloses a sheath fabricated from a flexible heat shrinking polymer, as recited in claim 6. As discussed above, Cochran in view of Kammerer fails to suggest the bag including "at least one transverse fold" recited in claim 1. Assuming, *arguendo*, that the characterization of Summer offered by the Examiner in the Office Action is accurate, including the sheath purportedly disclosed in Summer fails to cure the deficiencies of Cochran and/or Kammerer. Therefore, Applicant respectfully submits that Cochran in view of Kammerer and further in view of Summer fails to suggest each and every element recited in claim 1, and accordingly, that claim 1 is allowable over Cochran in view of Kammerer and further in view of Summer.

As claim 6 depends indirectly from claim 1 and contains all the elements thereof, for at least the reasons set forth above regarding the allowability of claim 1, *inter alia*, Applicant respectfully submits that claim 6 is also allowable over Cochran in view of Kammerer and further in view of Summer.

Claims 10-11 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cochran in view Kammerer and further in view of U.S. Patent No. 6,402,722 to Snow (hereinafter "Snow"). Applicant respectfully submits, however, that Cochran in view Kammerer and further in view of Snow fails to suggest each and every element recited in claims 10-11.

In the Office Action, it was asserted that Snow discloses the cord, and the features thereof, recited in claims 10-11. As discussed above, Cochran in view of Kammerer fails to suggest the bag including "at least one transverse fold" recited in claim 1. Assuming, *arguendo*, that the characterization of Snow offered by the Examiner in the Office Action is accurate, including the cord purportedly disclosed in Snow fails to cure the deficiencies of Cochran and/or Kammerer. Therefore, Applicant respectfully submits that Cochran in view of Kammerer and further in view of Snow fails to suggest each and every element recited in claim 1, and accordingly, that claim 1 is allowable over Cochran in view of Kammerer and further in view of Snow.

As claims 10-11 depend indirectly from claim 1 and contain all the elements thereof, for at least the reasons set forth above regarding the allowability of claim 1, *inter alia*, Applicant respectfully submits that claims 10-11 are also allowable over Cochran in view of Kammerer and further in view of Snow.

Applicant has added new claims 33-35 for consideration herein. Applicant respectfully submits that claims 33-35 add no new matter, are of a scope to which Applicant believes he is entitled, and are allowable over the references of record. For example, none of the references of

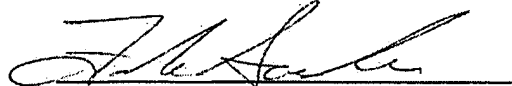
record, taken either individually or in any proper combination thereof, disclose or suggest a bag that is “repositionable between an unfolded position, in which the bag assembly defines an initial longitudinal dimension, and a folded position, in which the bag assembly defines a subsequent longitudinal dimension, the subsequent longitudinal dimension being greater than the initial longitudinal dimension,” as discussed above with respect to claims 1, 19, 28, and 31, or a method of collapsing a bag of a tissue removal device comprising the step of “folding the bag such that a first fold is formed, the first fold extending transversely with respect to the longitudinal axis,” as discussed above with respect to claim 19 in particular. (Emphasis added).

For at least these reasons, *inter alia*, Applicant respectfully submits that the references of record fail to disclose or suggest each and every element recited in new claim 33, and therefore, that new claim 33 is allowable. As claims 34-35 depend either directly or indirectly from claim 33 and contain all the elements thereof, for at least the reasons set forth regarding the allowability of claim 33, *inter alia*, Applicant respectfully submits that claims 34-35 are also allowable.

Should the Examiner believe that a telephone interview may facilitate prosecution of this application, the Examiner is respectfully requested to telephone Applicant's undersigned representative at the number indicated below.

In view of the foregoing amendments and remarks and arguments, reconsideration and allowance of the present application are earnestly solicited.

Respectfully submitted,



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